



**INFORMATION  
DISCLOSURE  
STATEMENT**

Atty. Docket No.: 275.00070101

Serial No.: 10/732,782

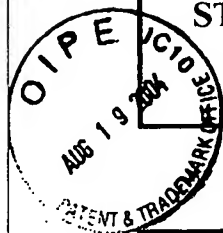
Applicant(s): Hsu et al.

Confirmation No.: 6883

Application Filing Date: 12/10/03

Group: 1614

Information Disclosure Statement mailed: \_\_\_\_\_


**U.S. PATENT DOCUMENTS**

Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
ASD		2003/0134300	07/17/03	Golub et al.			

**FOREIGN PATENT DOCUMENTS**

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No

**OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)**

Examiner Initial	Copy Enclosed	Document Description
ASD	✓	Ahmad et al., "Identification and Characterization of Murine Caspase-14, a New Member of the Caspase Family," <i>Cancer Res</i> , 1998;58: 5201-5205
	✓	Ahmad et al., "Green Tea Constituent Epigallocatechin-3-Gallate and Induction of Apoptosis and Cell Cycle Arrest in Human Carcinoma Cells," <i>J Natl Cancer Inst.</i> , 1997;89: 1881-1886
	✓	Appel et al., "Metabolic stability of experimental chemotherapeutic agents in hepatocyte: tumor cell co-cultures," <i>Cancer Chemother Pharmacol</i> , 1986;17: 47-52
	✓	Arteaga et al., "Transforming Growth Factor $\beta$ : Potential Autocrine Growth Inhibitor of Estrogen Receptor-negative Human Breast Cancer Cells," <i>Cancer Res</i> , 1988;48: 3898-3904
	✓	Azuma et al., "Immortalization of Normal Human Salivary Gland Cells with Duct-, Myoepithelial-, Acinar-, or Squamous Phenotype by Transfection with SV40 Ori-Mutant Deoxyribonucleic Acid," <i>Lab Invest</i> , 1993;69: 24-42
	✓	Bacus et al., "Neu differentiation factor (Heregulin) activates a p53-dependent pathway in cancer cells," <i>Oncogene</i> , 1996 12:2535-2547
	✓	Balasubramanian et al., "Green Tea Polyphenol Stimulates a Ras, MEKK1, MEK2, and p38 Cascade to Increase Activator Protein 1 Factor-dependent Involucrin Gene Expression in Normal Human Keratinocytes," <i>J Biol Chem</i> , 18 January 2002;277(3): 1828-1836

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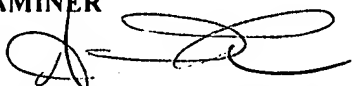
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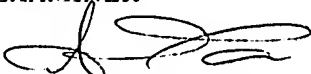
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ASD	✓	Barthelman et al., "(-)-Epigallocatechin-3-gallate inhibition of ultraviolet B-induced AP-1 activity," <i>Carcinogenesis</i> , 1998;(19)12:2201-2204
	✓	Bikle et al., "Calcium- and vitamin D-regulated keratinocyte differentiation," <i>Mol Cell Endocrinol</i> , 2001;177: 161-171
	✓	Blagosklonny et al., "Taxol Induction of p21 <sup>WAF1</sup> and p53 Requires c-raf-1," <i>Cancer Res</i> , 1995;55: 4623-4626
	✓	Blanc et al., "Caspase-3 Is Essential for Procaspase-9 Processing and Cisplatin-induced Apoptosis of MCF-7 Breast Cancer Cells", <i>Cancer Res</i> , 2000;60: 4386-4390
	✓	Bors et al., "Electron Paramagnetic Resonance Studies of Radical Species of Proanthocyanidins and Gallate Esters," <i>Arch Biochem Biophys</i> , 2000;374: 347-355
	✓	Bravo, "Polyphenols: Chemistry, Dietary Sources, Metabolism, and Nutritional Significance," <i>Nutri Rev</i> , 1998;56(11): 317-333
	✓	Cecconi, "Apaf1 and the apoptotic machinery," <i>Cell Death Diff.</i> , 1999; 6: 1087-1098
	✓	Chai et al., "Contribution of hydrogen peroxide to the cytotoxicity of green tea and red wines," <i>Biochem Biophys Res Commun</i> , 2003;304:650-654
	✓	Chang et al., "DOK, A Cell Line Established from Human Dysplastic Oral Mucosa, Shows a Partially Transformed Non-malignant Phenotype," <i>Int J Cancer</i> , 1992;52:896-902
	✓	Chaturvedi et al., "Apoptosis in Proliferating, Senescent, and Immortalized Keratinocytes," <i>J Biol Chem</i> , 13 August 1999;274(33): 23358-23367
	✓	Chen et al., "Activation of Antioxidant-Response Element (ARE), Mitogen-Activated Protein Kinases (MAPKs) and Caspases by Major Green Tea Polyphenol Components during Cell Survival and Death," <i>Arch Pharm Res</i> , 2000;23: 605-612
	✓	Chen et al., "Green tea epigallocatechin gallate shows a pronounced growth inhibitory effect on cancerous cells but not on their normal counterparts," <i>Cancer Lett.</i> , 1998;129:173-179

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APZ	✓	Chen et al., "Tea Catechins Protect against Lead-Induced Cytotoxicity, Lipid Peroxidation, and Membrane Fluidity in HepG2 Cells," <i>Toxicol Sci</i> , 2002;69: 149-156
	✓	Chung et al., "Inhibition of Activator Protein 1 Activity and Cell Growth by Purified Green Tea and Black Tea Polyphenols in H-ras-transformed Cells: Structure-Activity Relationship and Mechanism Involved," <i>Cancer Res</i> , 1999;59: 4610-4617
	✓	Cuvillier et al., "Sphingosine generation, cytochrome c release, and activation of caspase-7 in doxorubicin-induced apoptosis of MCF7 breast adenocarcinoma cells," <i>Cell Death Differ</i> , 2001;8: 162-71
	✓	Dashwood et al., "Inhibition of $\beta$ -catenin/Tcf activity by white tea, green tea, and epigallocatechin-3-gallate (EGCG): minor contribution of H <sub>2</sub> O <sub>2</sub> at physiologically relevant EGCG concentrations," <i>Biochem Biophys Res Commun</i> , 2002;296: 584-588
	✓	Deschenes et al., "Role of p27 <sup>Kip1</sup> in Human Intestinal Cell Differentiation," <i>Gastroenterology</i> , 2001;120: 423-438
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	✓	Dong, "Effects of food factors on signal transduction pathways," <i>Biofactors</i> , 2000;12: 17-28
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	✓	Dvorakova et al., "Pharmacokinetics of the green tea derivative, EGCG, by the topical route of administration in mouse and human skin," <i>Cancer Chemother Pharmacol</i> , 1999;43: 331-335
	✓	Eckhart et al., "Caspase-14: Analysis of Gene Structure and mRNA Expression during Keratinocyte Differentiation," <i>Biochem Biophys Res Commun</i> , 2000;277:655-659

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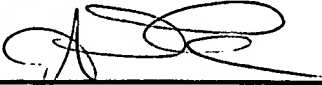
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ASP	✓	Eckhart et al., "Terminal Differentiation of Human Keratinocytes and Stratum Corneum Formation is Associated with Caspase-14 Activation," <i>J Invest Dermatol</i> , 2000;115:1148-1151
	✓	El-Mir et al., "In vitro test to determine the effect of cytostatic drugs on co-cultured rat hepatocytes and hepatoma cells," <i>Int J Exp Pathol</i> , 1998;79:109-115
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	✓	Halliwell, "Oxidative stress in cell culture: an under-appreciated problem?," <i>FEBS Lett</i> , 2003;540: 3-6
	✓	Harada et al., "Absence of the Type I IFN System in EC Cells: Transcriptional Activator (IRF-1) and Repressor (IRF-2) Genes are Developmentally Regulated," <i>Cell</i> , 1990;63: 303-312
	✓	Higdon, et al., "Tea Catechins and Polyphenols: Health Effects, Metabolism, and Antioxidant Functions," <i>Crit Rev Food Sci Nutr</i> , 2003;43(1): 89-143
	✓	Hong et al., "Stability, Cellular Uptake, Biotransformation, and Efflux of Tea Polyphenol (-)-Epigallocatechin-3-Gallate in HT-29 Human colon Adenocarcinoma Cells," <i>Cancer Res.</i> , 2002;62: 7241-7246
	✓	Hsu et al., "Green Tea Polyphenol Targets the Mitochondria in Tumor Cells Inducing Caspase 3-Dependent Apoptosis," <i>Anticancer Res</i> , 2003; 23:1533-1540
	✓	Hsu et al., "Green Tea Polyphenols Induce Differentiation and Proliferation in Epidermal Keratinocytes," <i>J Pharmacol Exp Ther</i> , 2003;306: 29-34
	✓	Hsu et al., "Chemoprevention of oral cancer by green tea." <i>General Dentistry</i> , 2002 Mar-Apr;50(2): 140-146

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ASD	✓	Hsu et al., "Chemopreventive effects of green tea polyphenols correlate with reversible induction of p57 expression," <i>Anticancer Research</i> , 2001 Nov-Dec;21(6A): 3743-3478.
	✓	Hsu et al., "Induction of p57 is required for cell survival when exposed to green tea polyphenols," <i>Anticancer Research</i> , 2002 Nov-Dec;22(6C): 4115-4120
	✓	Hsu et al., "Chemopreventive effects of green tea polyphenol is associated with caspase 14 induction in epidermal keratinocytes," AACR Annual Meeting, Orlando, Fl., March 29, 2004. Abstract
	✓	Hu et al., "Caspase-14 Is a Novel Developmentally Regulated Protease," <i>J Biol Chem</i> , 6 November 1998;273(45): 29648-29653
	✓	Huang et al., "Inhibitory effect of topical application of a green tea polyphenol fraction on tumor initiation and promotion in mouse skin," <i>Carcinogenesis</i> , 1992;13(6): 947-954
	✓	Huynh et al., <i>Journal of Dental Research</i> , 201;80: 176
	✓	Irwin et al., "Role for the p53 homologue p73 in E2F-1-induced apoptosis," <i>Nature</i> , 2000;407: 645-648
	✓	Ishii et al., "Prevention of Mammary Tumorigenesis in Acatalasemic Mice by Vitamin E Supplementation," <i>Jpn J Cancer Res</i> , 1996;87: 680-684
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	✓	Ito et al., "Expression of p57/Kip2 protein in extrahepatic bile duct carcinoma and intrahepatic cholangiocellular carcinoma," <i>Liver</i> , 2000;22: 145-149
	✓	Ito et al., "Expression of p57/Kip2 Protein in Hepatocellular Carcinoma," <i>Oncology</i> , 2001;61: 221-225
	✓	Ito et al., "Expression of p57/Kip2 Protein in Pancreatic Adenocarcinoma," <i>Pancreas</i> , 2001;23(3): 246-50
	✓	Ito et al., "Expression of p57/Kip2 protein in normal and neoplastic thyroid tissues," <i>Int J Mol Med</i> , 2002;9: 373-376

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ASD	✓	Janicke et al., "Caspase-3 Is Required for DNA Fragmentation and Morphological Changes Associated with Apoptosis," <i>J Biol Chem</i> , 17 April 1998;273(16): 9357-9360
	✓	Jin et al., "Different Effects of Five Catechins on 6-Hydroxydopamine-Induced Apoptosis in PC12 Cells," <i>J Agric Food Chem</i> , 2001;49: 6033-6038
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	✓	Kagawa et al., "Deficiency of Caspase-3 in MCF7 Cells Blocks Bax-mediated Nuclear Fragmentation but not Cell Death," <i>Clin Cancer Res</i> , 2001;7:1474-1480
	✓	Katiyar et al., "Inhibition of UVB-induced oxidative stress-mediated phosphorylation of mitogen-activated protein kinase signaling pathways in cultured human epidermal keratinocytes by green tea polyphenol(-)-epigallocatechin-3-gallate," <i>Toxicol Appl. Pharmacol</i> , 2001;176: 110-117
	✓	Katiyar et al., "Green tea polyphenol (-)-epigallocatechin-3-gallate treatment of human skin inhibits ultraviolet radiation-induced oxidative stress," <i>Carcinogenesis</i> , 2001;22(2): 287-294
	✓	Katiyar, et al., "Green Tea Polyphenolic antioxidants and skin photoprotection (Review)," <i>Int J Oncol</i> , 2001;18:1307-1313
	✓	Kennedy et al., "Growth inhibitory effect of green tea extract in Ehrlich ascites tumor cells involves cytochrome c release and caspase activation," <i>Cancer Lett</i> , 2001;166: 9-15
	✓	King, et al., "Characteristics and occurrence of phenolic phytochemicals," <i>J Am Diet Assoc</i> , 1999;99:213-218
	✓	Kiningham, et al., "Overexpression of Manganese Superoxide Dismutase Selectively Modulates the Activity of Jun-associated Transcription Factors in Fibrosarcoma Cells," <i>Cancer Res</i> , 1997;57: 5265-5271
	✓	Kong et al., "Differential Activation of MAPK and ICE/Ced-3 Protease in Chemical-Induced Apoptosis," <i>Restor Neurol Neurosci</i> , 1998;12: 63-70

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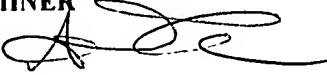
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ASD	✓	Lambert, et al., "Cancer chemopreventive activity and bioavailability of tea and tea polyphenols," <i>Mutat Res</i> , 2003 Feb- Mar;523-524: 201-208
	✓	Lapp et al., "Macroarray analysis of tea polyphenol-treated normal versus malignant epithelial cells" Medical College of Georgia School of Denistry, USA. AADR Annual Meeting, Honolulu, HI. March 12, 2004.
	✓	Lee et al., "Cloning of p57 <sup>KIP2</sup> , a cyclin-dependent kinase inhibitor with unique domain structure and tissues distribution," <i>Genes Dev</i> , 1995;9: 639-649
	✓	Lee et al., "Differentiation of Cultured Human Epidermal Keratinocytes at High Cell Densities is Mediated by Endogenous Activation of The Protein Kinase C Signaling Pathway," <i>J Invest Dermatol</i> , 1998;111(5): 762-766
	✓	Lee et al., "Inhibition of 1,2,4-benzenetriol-generated active oxygen species and induction of phase II enzymes by green tea polyphenols," <i>Chem Biol Interact</i> , 1995;98: 283-301
	✓	Lee et al., "Protective Effect of Green Tea Polyphenol (-)-Epigallocatechin Gallate and Other Antioxidants on Lipid Peroxidation in Gerbil Brain Homogenates," <i>Phytother Res</i> , 2003;17:206-209
	✓	Leist, et al., "Four Deaths and a Funeral: From Caspases to Alternative Mechanisms," <i>Nat Rev Mol Cell Bio</i> , 2001;2:589-98
	✓	Liberto, et al., "Growth factor-dependent induction of p21 <sup>CIP1</sup> by the green tea polyphenol, epigallocatechin gallate," <i>Cancer Lett</i> , 2000;154: 151-161
	✓	Lin et al., "Cancer Chemoprevention by Tea Polyphenols through Mitotic Signal Transduction Blockade," <i>Biochem Pharmacol</i> , 1999;58: 911-915
	✓	Lippens et al., "Epidermal differentiation does not involve the pro-apoptotic executioner caspases, but is associated with caspase-14 induction and processing," <i>Cell Death Differ.</i> , 2000;7:1218-1224
	✓	Lissy et al., "A common E2F-1 and p73 pathway mediates cell death induced by TCR activation," <i>Nature</i> , 2000; 407: 642-5
	✓	Long et al., "Generation of Hydrogen Peroxide by "Antioxidant" Beverages and the Effect of Milk Addition. Is Cocoa the Best Beverage?," <i>Free Rad Res</i> , 1999;31: 67-71

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ASD	✓	Makino et al., "Evaluation of Quantitative Detection of mRNA by the reverse transcription-polymerase chain reaction," <i>Technique</i> , 1990;2: 295-301
	✓	Martinez et al., "Coordinated changes in cell cycle machinery occur during keratinocyte terminal differentiation," <i>Oncogene</i> , 1999;18: 397-406
	✓	Milton, "Nutritional Characteristics of Wild Primate Foods: Do the Diets of our Closest Living Relatives Have Lessons for Us?," <i>Nutrition</i> , 1999;15(6): 488-498
	✓	Missero et al., "Involvement of the cell-cycle inhibitor <i>Cip1/WAF1</i> and the E1A-associated p300 protein in terminal differentiation," <i>Proc Natl Acad Sci USA</i> , June 1995;92: 5451-5455
	✓	Miyazawa, "Absorption, metabolism and antioxidative effects of tea catechin in humans," <i>Biofactors</i> , 2000;13: 55-59
	✓	Moroni et al., "Apaf-1 is a transcriptional target for E2F and p53," <i>Nat Cell Biol</i> , 2001;3:552-8
	✓	Nakagawa et al., "Fenton Reaction is Primarily Involved in a Mechanism of (-)-Epigallocatechin-3-gallate to Induce Osteoclastic Cell Death," <i>Biochem Biophys Res Comm</i> , 2002;292: 94-101
	✓	Nepka et al., "Tannins, xenobiotic metabolism and cancer chemo-prevention in experimental animals," <i>Eur J Drug Metal Pharmacokinet</i> , 1999;24(2): 183-189
	✓	Nie et al., "Distinct Effects of Tea Catechins on 6-Hydroxydopamine-Induced Apoptosis in PC 12 Cells," <i>Arch Biochem Biophys</i> , 2002;397(1): 84-90
	✓	Nishimori et al., "Smad -mediated Transcription Is Required for Transforming Growth Factor- $\beta$ 1-induced p57 <sup>Kip2</sup> Proteolysis in Osteoblastic Cells," <i>J Biol Chem</i> , 6 April 2001;276(14): 10700-10705
	✓	Osaki et al., "Tumorigenicity of cell lines established from oral squamous cell carcinoma and its metastatic lymph nodes," <i>Eur J Cancer B, Oral Oncol</i> , 1994;30B(5): 296-301
	✓	Pan et al., "Induction of Apoptosis by the Oolong Tea Polyphenol Theasinensin A through Cytochrome c Release and Activation of Caspase-9 and Caspase-3 in Human U937 cells," <i>J Agric Food Chem</i> , 2000;48: 6337-6346

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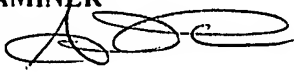
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ASD	✓	Parkin et al., "Global Cancer Statistics," <i>CA Cancer J Clin</i> , 1999;49:33-64
	✓	Parkin et al., "Estimates of the Worldwide Incidence of Eighteen Major Cancers in 1985," <i>International J. of Cancer</i> , 1993;54:594-606
	✓	Paschka et al., "Induction of apoptosis in prostate cancer cell lines by the green tea component, (-)-epigallocatechin-3-gallate," <i>Cancer Lett</i> , 1998;130: 1-7
	✓	Pingzhang et al., "Experimental studies of the inhibitory effects of green tea catechin on mice large intestinal cancers induced by 1,2-dimethylhydrazine," <i>Cancer Lett</i> , 1994;79: 33-38
	✓	Pistritto et al., "Expression and transcriptional regulation of caspase-14 in simple and complex epithelia," <i>Cell Death Differ.</i> , 2002;9: 995-1006
	✓	Rendl et al., "Caspase-14 Expression by Epidermal Keratinocytes is Regulated by Retinoids in a differentiation-associated Manner," <i>J Invest Dermatol.</i> , 2002;119:1150-1155.
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	✓	Roy et al., "Anticlastogenic, antigenotoxic and apoptotic activity of epigallocatechin gallate: a green tea polyphenol," <i>Mutat Res</i> , 2003; 523-524: 33-41
	✓	Ruch et al., "Prevention of cytotoxicity and inhibition of intercellular communication by antioxidant catechins isolated from Chinese green tea," <i>Carcinogenesis</i> , 1989;10(6): 1003-1008
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	✓	Saeki et al., "Oxidation-triggered c-Jun N-terminal kinase (JNK) and p38 mitogen-activated protein (MAP) kinase pathways for apoptosis in human leukaemic cells stimulated by epigallocatechin-3-gallate (EGCG): a distinct pathway from those of chemically induced and receptor-mediated apoptosis," <i>Biochem J</i> , 2002;368: 705-720

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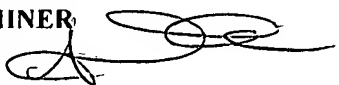
<b>INFORMATION DISCLOSURE STATEMENT</b>	<b>Atty. Docket No.:</b> 275.00070101	<b>Serial No.:</b> 10/732,782
	<b>Applicant(s):</b> Hsu et al.	<b>Confirmation No.:</b> 6883
	<b>Application Filing Date:</b> 12/10/03	<b>Group:</b> 1614
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ASD	✓	Sakagami et al., "Productin of Hydrogen Peroxide and Methionine Sulfoxide by Epigallocatechin Gallate and Antioxidants," <i>Anticancer Res</i> , 2001;21: 2633-2642
	✓	Shen et al., "Green Tea Catechins Evoke a Phase Contraction in Rat Aorta via H <sub>2</sub> O <sub>2</sub> -Mediated Multiple-Signalling Pathways," <i>Clin Exp Pharmacol Physiol</i> , 2003;30: 88-95
	✓	Soengas et al., "Inactivation of the apoptosis effector Apaf-1 in malignant melanoma," <i>Nature</i> , 2001; 409: 207-211
	✓	Stoner, et al., "Polyphenols as Cancer Chemopreventive Agents," <i>J Cell Biochem Supp</i> , 1995;22: 169-180
	✓	Stratton et al., "Dermal toxicity of topical (-)epigallocatechin-3-gallate in BALB/c and SKH1 mice," <i>Cancer Lett</i> , 2000;158: 47-52
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	✓	Suganuma et al., "Synergistic Effects of (-)-Epigallocatechin Gallate with (-)-Epicatechin, Sulindac, or Tamoxifen on Cancer-preventive Activity in the Human Lung Cancer cell Line PC-9 <sup>1</sup> ," <i>Cancer Res</i> , 1999;59: 44-47
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	✓	Yamamoto et al., "Green Tea Polyphenol causes differential oxidative environments in Tumor versus Normal Epithelial Cells," <i>J Pharmacol Exp Ther</i> , 3 September 2003;307: 230-236
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AsD	✓	Yan et al., "Ablation of the CDK inhibitor p57 <sup>Kip2</sup> results in increased apoptosis and delayed differentiation during mouse development," <i>Genes Dev.</i> , 1997;11: 973-983
	✓	Yang et al., "Inhibition of growth and induction of apoptosis in human cancer cell lines by tea polyphenols," <i>Carcinogenesis</i> , 1998;19(4):611-616
	✓	Yang et al., "Human salivary tea catechin levels and catechin esterase activities: implication in human cancer prevention studies," <i>Cancer Epidemiol Biomarkers Prev</i> , 1999;8: 83-89
	✓	Yang et al., "Effect of black and green tea polyphenols on c-jun phosphorylation and H <sub>2</sub> O <sub>2</sub> production in transformed and non-transformed human bronchial cell lines: possible mechanisms of cell growth inhibition and apoptosis induction," <i>Carcinogenesis</i> , 2000;21(11): 2035-2039
	✓	Yokoyama et al., "Inhibitory effect of epigallocatechin-gallate on brain tumor cell lines in vitro," <i>Neuro-oncol.</i> , 2001;3: 22-28
	✓	Yoneda et al., "p53 Gene mutations and p21 protein expression induced independently of p53, by TGF- $\beta$ and $\gamma$ -rays in squamous cell carcinoma cells," <i>Eur J Cancer</i> , 1999;35(2):278-283
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